REMARKS

Amendments to the Specification

The specification has been amended to correct typographical errors. Specifically, "individum" on page 1 has been changed to "individual," and "(hereinafter: EGCG)" is now placed after the first instance of "epigallocatechin gallate". The last comma at the end of paragraph 12 has been replaced with a period. In paragraph 52, the trademark TURRAX has been properly capitalized.

Status of the Claims

The Examiner stated that "[c]laims 1-13, 16, 19 and 20 [are] withdrawn from further consideration as being drawn to a nonelected invention or species, there being no allowable generic or linking claim." (Id.). Claim 16 is the only withdrawn claim that falls within the elected Group III claims as it does not recite the elected species, ligustilide.

As the Examiner determines that the claims drawn to the elected ligustilide species are deemed allowable, removal of the "withdrawn" designation of claim 16 is respectfully requested, in accordance with MPEP § 1893.03(d).

Objection to the Specification

The Examiner objected to the specification because of informalities including typographical errors and the use of a trademark that was not written in capital letters, in the Office Action of July 25, 2007 (Paper No. 20070713 at 2). In response, Applicants have amended the specification as discussed above under the heading, Amendments to the Specification. As the informalities have been corrected by amendment, withdrawal of the objection to the specification is requested.

Amendments to the Claims

Claim 14 has been amended to recite a composition comprising a catechin found in green tea, and a peroxisome proliferator-activated receptor gamma (PPARγ) ligand selected from the group consisting of thiazolidinediones, ligustilide and phytanic acid, "wherein the composition is a pharmaceutical composition." Support for this amendment may be found in the specification at, for example, page 1, paragraph 2; and page 2, paragraph 12, lines 1-9 of Published Application US2007/0042057 ("the Specification").

Claim 18 has been canceled, without prejudice.

Claims 21-23 have been added. New claim 21 depends from amended claim 14 and recites that the PPARγ ligand is ligustilide. Support for new claim 21 is found at page 1, paragraph 2; and page 2, paragraph 12, lines 1-9; page 2, paragraph 21; page 2, paragraph 15, lines 1-3.

New claim 22 depends from amended claim 14 and recites that the PPARγ ligand is in a dosage of from about 1 to about 1000 mg. Support for new claim 22 may be found in the Specification at, for example, page 2, paragraph 17, lines 1 and 6-9.

New claim 23 depends from amended claim 14 and recites that the pharmaceutical composition is a solid unit oral dosage form. Support for new claim 23 may be found in the Specification at, for example, page 1, paragraph 2, line 7-10; page 2, paragraph 12, lines 1-3; and page 2, paragraph 11, lines 1-2.

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

Claim Objection:

Claim 18 was objected to because of an informality. (Paper No. 20070713 at 3). Because of the cancellation of claim 18, the objection to claim 18 has been rendered moot. Therefore, it is respectfully submitted that the objection should be withdrawn.

Double Patenting:

In a first double patenting rejection, claims 14-15 and 17-18 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting. (Id. at 4). The Examiner stated that claims 14-15 and 17-18 of the instant application are "unpatentable over claims 1-20 of copending Application No. 10/525,348 [("the '348 application")]." (Id.) In making the rejection, the Examiner stated that "the conflicting claims are not identical, [but] they ... each are drawn to a composition comprising epigallocatechin gallate and the non-elected species phytanic acid." (Id.)

In a second double patenting rejection, claims 14-15 and 17-18 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as "unpatentable over claims 25-45 of copending Application No. 10/533,585." (Id.) In making the rejection, the Examiner stated that each set of claims is "drawn to a composition comprising [EGCG] and the non-elected species phytanic acid." (Id.)

The application cited by the Examiner in the second double patenting rejection, U.S. Application No. 10/533,585, is entitled Recording/Reproduction Device and Method and it does not relate to the subject matter alleged by the Examiner. It is

believed that the Serial No. cited contains a typographical error. Accordingly, the second double patenting rejection is improper and should be withdrawn.

In the interests of furthering prosecution, Applicants have identified U.S. Serial No. 10/533,858 ("the '858 application") which discloses neutraceutical compositions related to EGCG and phytaninc acid. Applicants presume that the Examiner meant to cite U.S. Serial No. 10/533,858, and will respond accordingly.

In a third double patenting rejection, claims 14-15 and 17-18 were provisionally rejected on the ground of non-statutory obviousness-type double patenting over claims 13 and 15-24 of copending Application No. 10/556,199 ("the '199 application") in view of Hara et al. U.S. Patent No. 5,318,986 ("Hara"). The Examiner stated that "Application No. 10/556,199 teaches a composition comprising ligustilide", and such "composition is used in [presently] withdrawn claims to treat diabetes. (Id.) The Examiner further stated that "Hara ... teaches the use of a composition comprising [EGCG] to treat diabetes." (Id.) The Examiner concluded that making the combination of ligustilide with EGCG "would have been obvious". (Id. at 4-5).

The rejections are respectfully traversed. The following remarks address all three provisional double patenting rejections.

Initially, it is noted that claim 18 has been cancelled. Thus, all of the provisional double patenting rejections have been rendered moot with respect to this claim and should be withdrawn.

An obviousness-type double patenting analysis is an obviousness analysis, and it must follow and be based on each of the *Graham* factors. *See Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.*, 228 USPQ 837, 840,

cert. dismissed, 478 U.S. 1028 (1986); and *Pac-Tec, Inc. v. Amerace Corp.*, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990); *In re Braat*, 19 USPQ2d 1289, 1292 (Fed. Cir. 1991); *In re Braithwaite*, 154 USPQ 29, 34 n. 4 (CCPA 1967). As the Office Action reflects, while the Examiner acknowledged that the pending claims differ from the claims of each of the '348 application, the '858 application, and the '199 application, yet the Office Action failed to make clear ***why*** one of ordinary skill in the art "would conclude that the invention defined in the claim at issue ... would have been an obvious variation of the invention defined in a claim in the patent." MPEP § 804(II)(B)(1) (8th ed. Rev. 6, Sept. 2007, pp 800-21 to 800-22).

Additionally, the rejection of the claims in this application over the claims of each of the '348 application, the '858 application and the '199 application fails to make **a claim-by-claim comparison and analysis**. As the Federal Circuit explained, a "double patenting challenge must be evaluated, like any other ground of invalidity, **against individual claims**." *Ortho Pharmaceutical Corp. v. Herchel Smith* 22 USPQ2d 1119 (Fed. Cir. 1992). *See also* MPEP § 804. As for each of the first two double patenting rejections, the Examiner *only* asserted that "each [set of claims] are drawn to a composition comprising epigallocatchin gallate and the non-elected species phytanic acid," which is simply not enough to set forth a *prima facie* case of obviousness-type double patenting. (Paper No. 20070713 at 4). With regard to the third double patenting rejection, the Examiner *only* asserted that making the combination of ligustilide with EGCG "would have been obvious" over the '199 application in view of Hara. (Id.)

Thus, it respectfully is submitted that because the rejection is deficient as a matter of fact and law, it should be withdrawn.

In addition, claim 14 has been amended to recite "wherein the composition is a pharmaceutical composition." Claims 15 and 17 depend from claim 14. New claims are also added. It is respectfully submitted that the present claim coverage is not obvious over the claims cited by the Examiner in the first two double patenting rejections, nor is it obvious over the claims cited by the Examiner in view of Hara with regard to the third double patenting rejection.

In addition to the foregoing, all three double patenting rejections were provisionally made. Accordingly, no terminal disclaimer is required at this time in response to any of these rejections. Should at least one of these rejections be the only remaining rejection, and the claims upon which the rejection(s) are based still pending, Applicants would then explore the possibility of submitting a terminal disclaimer. Until such time, requiring a terminal disclaimer is premature. *See* MPEP §§ 804(I)(B)(1) (8th ed. Rev. 6, Sept. 2007, pp. 800-17 to 800-18).

Rejection under 35 USC §102:

Claims 14-15 and 17-18 have been rejected under 35 USC § 102(b) as being anticipated by Cui, CN 1120953 ("Cui"), with evidence provided by Ahmad et al. Nutritional Reviews, March 1999 ("Ahmad") and Ko, Japanese Journal of Pharmacology, February 1980 ("Ko"). (Paper No. 20070713 at 5).

For the reasons set forth below, the rejection respectfully is traversed.

Cui discloses, "Glossy ganoderma drink is a bagged drink, which mainly contains (%): Glossy ganoderma sporophore 50-70, Wuyuan green tea 10-25, Ligusticum wallichii 5-12, red sage 1-10 and safflower 1-5." (Abstract, 1st paragraph). Cui further discloses, "USE – The drink has obvious hypolipeamic, blood pressure

depressing and hypoglycaemic functions, can improve microcirculation and can prevent and cure coronary heart disease, heart disease and other cardiovascular diseases as well as cancer." (Abstract, 2nd paragraph).

In making the anticipation rejection, the Examiner asserted that "Cui teaches a composition containing green tea (10-25%) and *Ligusticum wallichii* (5-12%) out of 5 total ingredients as a health-benefiting drink." (Id. at 6). The Examiner stated that Ahmad provides evidence that "[g]reen tea is known to be an excellent source of catechins", and that "[e]pigallocatchin gallate is the major catechin found in green tea...". (Id.) The Examiner determined that "one cup of this composition [disclosed by Cui] would contain 20-50 mg of epigallocatechin gallate." (Id.) The Examiner also stated that Ko provides evidence that "*Ligusticum wallichii* is known to contain several phthalide compounds, one of which is ligustilide...". (*Id.*). The Examiner concluded that "the composition taught by Cui would inherently contain ligustilide." (Id.)

As is well settled, anticipation requires "identity of invention." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply,* 33 USPQ2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.,* 221 USPQ 481, 485 (Fed. Cir 1984). There must be no difference between what is claimed and what is disclosed in the applied reference. *In re Kalm*, 154 USPQ 10, 12 (CCPA 1967); *Scripps v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991).

Initially, it is noted that claim 18 has been canceled. Therefore, the rejection with respect to claim 18 has been rendered moot and should be withdrawn.

Cui discloses at least five ingredients that are herbs, botanicals or other naturally occurring substances in a beverage as a "health-benefiting drink", as referred to by the Examiner. Each of the identified ingredients may contain numerous chemical substances. And, although the Examiner has asserted that Wuyuan green tea and *Ligusticum wallichii* each contain a component recited in the present claims, it is noted that Cui also requires the presence of Glossy ganoderma sporophore (in the largest percentage of any ingredient), red sage and safflower. The Cui disclosure lacks an "identity of invention" with the claimed composition which comprises a catechin found in green tea, and a peroxisome proliferator-activated receptor gamma (PPARγ) ligand selected from the group consisting of thiazolidinediones, ligustilide and phytanic acid.

Furthermore, in a §102(b) rejection there must be no difference between what is claimed and what is disclosed in the applied reference. *In re Kalm*, 154 USPQ 10, 12 (CCPA 1967); *Scripps v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991).

With a view towards furthering prosecution, claim 14 has been amended to recite that "the composition is a pharmaceutical composition." Cui's disclosure of a beverage or "health-benefiting drink", as referred to by the Examiner, fails to identify each and every element of the amended claims. No disclosure of a pharmaceutical composition is provided by Cui. For this reason alone, the rejection should be withdrawn as to claims 14, 15 and 17.

New claims 21-23 depend from amended claim 14 which recites a pharmaceutical composition. It is respectfully submitted that Cui's beverage cannot anticipate these new claims.

Rejection Under 35 USC § 103:

Claims 14-15 and 17-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Cui with evidence provided by Ahmad and Ko. (Paper No. 20070713 at 7). The Examiner stated that "Cui beneficially teaches a composition comprising green tea (10-25%) and *Ligusticum wallichii* (5-12%) out of 5 total ingredients as a health-benefiting drink." (Id.). The Examiner restated what was said about Cui in the § 102 rejection. These statements by the Examiner are summarized above in response to the § 102 rejection. In short, the Examiner asserted that Cui's disclosed composition would inherently contain ligustilide and catechins, including epigallocatchin gallate at an amount of 20-50 mg per cup. (Paper No. 20070713 at 7-8).

The Examiner then concluded, "It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a health-benefiting beverage comprising the instantly claimed components of catechins found in green tea, such as epigallocatechin gallate, and ligustilide, found in *Ligusticum wallichii* based on the beneficial teachings of Cui." (Paper No. 20070713 at 8). The Examiner also stated that "determining the amounts of green tea and *Ligusticum wallichii* and thus the amounts of [EGCG] and ligustilide respectively that would be health-benefiting ... is deemed merely a matter of judicious selection and routine optimization..." (Id.) The Examiner added that "one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention." (Id.). The Examiner concluded that "the invention as a whole was prima facie obvious ... as evidenced by the references, especially in the absence of evidence to the contrary." (Id.).

Cui discloses at least five ingredients that are herbs, botanicals or other natural ingredients in a beverage as a "health-benefiting drink", as referred to by the Examiner. According to Cui, there may be more than five ingredients, as the sum of the lowest percentage range for each of the disclosed ingredients of Cui is 67%. And, each of the identified ingredients may contain numerous chemical substances. For example, Glossy ganoderma sporophore (which is present in the largest percentage of any ingredient), a dried sporophore of *Ganodera licidum*, includes "polycose, sterol, triterpenes, amino acids, etc.", according to an on-line site about "Commonly Used Single Chinese Medicinal Herbs". http://beijingmuseum.gov.cn/materia/single/75751.shtml , a copy of which is enclosed as Exhibit 1 (see page 2).

In another example, Ko, cited by the Examiner as evidentiary support, indicates that there are at least three chemical compounds found in *Ligusticum wallichii Franch*, as Ko discloses that the following three were isolated therefrom: butylidenephthalide (BdPh), ligustilide and butylphthalide. (Ko, Abstract and the first paragraph). Moreover, although the Examiner has asserted that Wuyuan green tea and *Ligusticum wallichii* each contain a component recited in the present claims, it is noted that Cui also requires the presence of Glossy ganoderma sporophore, mentioned above, as well as red sage and safflower.

Thus, Cui can best be understood as generically embracing elements of the claimed composition, since Cui's at least five ingredients consist of a multitude of compounds, ***only two*** of which are recited in the claims of the present invention. A "generic" disclosure by itself is simply insufficient to satisfy the PTO's burden to

demonstrate that what is claimed is obvious. As is well settled, a "generic" disclosure does not render everything within its scope obvious. See *Ex parte Rozzi*, 63 USPQ2d at 1201 ("The Examiner does not make out a case of obviousness merely by virtue of the fact that the subject matter of a rejected claim is, to use the Examiner's words, 'generically' described by the prior art."); *In re Baird*, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994) ("the fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious"); *In re Deuel*, 34 USPQ2d 1210, 1215 (Fed. Cir. 1995); *In re Jones*, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992) ("we decline to extract from Merck the rule that . . . regardless of how broad, a disclosure of a chemical genus renders obvious any species that happens to fall within it"); *Ex parte Garvey*, 41 USPQ 583, 584 (Bd. App. 1939) ("producing a composition as claimed . . . would be about the same as the likelihood of discovering the combination of a safe from a mere inspection of the dials."); and *In re Luvisi*, 144 USPQ 646, 649-50 (CCPA 1965) (the reference presents "a 'needle-in-the-haystack' type of disclosure").

In the present case, Cui provides a proverbial haystack of chemical compounds in the disclosure of the at least five ingredients of the "health-benefiting beverage", which translates into hundreds if not thousands of chemical compounds, yet there is no reference that points to the needle — the two claimed compounds — in the haystack. Of the three substances that Ko isolated from *Ligusticum wallichii*, Ko chose to study the effects of BdPh rather than ligustilide. (Id., entire article). In view of overwhelming decisional authority, it is respectfully submitted that the rejection is legally insufficient and must be withdrawn for this reason alone.

With a view towards furthering prosecution, claim 14 has been amended to recite a composition comprising a catechin found in green tea, and a peroxisome proliferator-activated receptor gamma (PPARγ) ligand selected from the group consisting of thiazolidinediones, ligustilide and phytanic acid, "wherein the composition is a pharmaceutical composition." Cui's disclosure is of a beverage or "health-benefiting drink", as referred to by the Examiner. The ingredients are herbs, botanicals or other naturally occurring substances. No disclosure of a pharmaceutical composition is provided by Cui. Nor is there any teaching, suggestion or motivation provided by Cui for a pharmaceutical composition. For this reason alone, the rejection should be withdrawn as to claims 14, 15 and 17.

As indicated above, in the at least five ingredients of Cui's beverage, Cui essentially provides a mixture of hundreds if not thousands of compounds. There is no teaching, suggestion or motivation provided by Cui to pick out of these numerous compounds a catechin found in green tea, and a peroxisome proliferator-activated receptor gamma (PPARγ) ligand selected from the group consisting of thiazolidinediones, ligustilide and phytanic acid, for preparation of a pharmaceutical composition.

Additionally, the claimed combination provides unexpectedly improved and superior results, which would not have been obvious to a person having ordinary skill in the art. Although PPARγ agonists are known to have beneficial effects on glucose homeostasis, their use is not considered optimal in long-term treatment of type 2 diabetes because concomitant weight gain could compromise the positive effects of treatment. (See the Specification, pages 2-3, paragraph 9). Regarding the

combination in accordance with the present invention, however, the Specification discloses:

> ...**it has surprisingly been found that the combination of EGCG and PPARγ ligands results in amelioration and/or elimination of the undesirable side effect of PPARγ agonist-induced adipocyte differentiation, which leads to body fat gain**. Thus, PPARγ ligands ... can be used, in combination with EGCG to treat Type 2 diabetes mellitus and to inhibit/reduce the PPARγ agonist-induced adipogenesis, while maintaining or increasing the glucose lowering effects.
>
> (Page 2, paragraph 10) (emphasis added).

All of the experimentals of Example 1 demonstrate these findings. It is noted that adipocyte differentiation testing is based on the premise that increased fat cell differentiation results in body fat accumulation in humans.

TABLE

Ligustilide and EGCG: Effects on Adipocyte Differentiation

	OD
I	0.14 ± 0.01
I + L	0.26 ± 0.01
I + L + EGCG (1×10^{-5} M)	0.18 ± 0.01
I + L + EGCG (50×10^{-5} M)	0.11 ± 0.01
I + L + EGCG (1×10^{-4} M)	0.12 ± 0.01

Key:
I = Insulin (100 nm)
L = Ligustilide (50×10^{-5} M)
OD = Optical Density

Ligustilide, the elected species, is addressed in Example 1, section B, at pages 2-3, paragraphs 22-24 including Table 2 of the Specification. The subject matter

of Table 2 which follows paragraph 23 on page 3 of the Specification is provided here as follows:

As would be expected, "[c]o-treatment of ... cells with ligustilide and insulin resulted in a higher differentiation of these cells into adipocytes than insulin alone...". (Pages 2-3, paragraph 23). This is shown by the significantly higher optical density (OD) with insulin and ligustilide, 0.26 +/- 0.001, as compared to insulin alone, 0.14 +/- 0.001.

"Co-treatment with insulin, ligustilide and several concentrations of EGCG", however, "resulted in a dose-dependent reduction of adipocyte differentiation." (Page 3, paragraph 23). The insulin, ligustilide and EGCG (1×10^{-5} M) formulation resulted in an OD of 0.18 +/- 0.01. Thus, the presence of EGCG (1×10^{-5} M) in the formulation with ligustilide resulted in a ***significant lowering of adipocyte differentiation of 30.8%*** as compared to ligustilide without EGCG (having an OD of 0.26 +/-0.001). Furthermore, the insulin, ligustilide and EGCG (50×10^{-5} M) formulation and the insulin, ligustilide and EGCG (1×10^{-4} M) formulation resulted in OD's of 0.11 +/- 0.01 and 0.12 +/- 0.01, respectively. Thus, the presence of EGCG (50×10^{-5} M) and EGCG (1×10^{-4} M) in the formulation with ligustilide resulted in a ***significant lowering of adipocyte differentiation of 57.7% and 53.8%,*** respectively, as compared to ligustilide without EGCG (having an OD of 0.26 +/-0.001). The Specification summarizes that "[t]he above results show that EGCG blocked ligustilide-induced adipocyte differentiation. Thus the combination of EGCG and the PPARγ ligand ligustilide allows a treatment that prevents progression of type 2 diabetes, while sumultaneously minimizing side effects of PPARγ ligands." (Page 3, paragraph 24).

It is respectfully submitted that the claimed pharmaceutical composition has been shown to be unobvious. Moreover, patentability of claims to a pharmaceutical composition encompassing the elected species ligustilide is thus fully supported.

As indicated under the Status of the Claims section above, Applicants request that the Examiner consider claim 16 for rejoinder. Claim 16 recites that the thiazolidinedione is ciglitazone, rosiglitazone or pioglitazone. Example 1 of the Specification includes experimentals testing rosiglitazone and pioglitazone which also support the patentability of the claims under consideration.

In Example 1A, combinations were tested to determine the effect on adipocyte differentiation as discussed above regarding Example 1B for ligustilide. Combinations of EGCG and rosiglitazone or EGCG and pioglitazone, however, were used in Example 1A. Applicants refer the Examiner to page 2, paragraphs 19-21, including the data presented in Table 1 which provides unexpectedly improved and superior results. For example, adipocyte differentiation tested with rosiglitazone and EGCG (and insulin) was lowered by about 16% as compared to rosiglitazone (and insulin) with comparative OD values of 0.25 +/- 0.01 and 0.30 +/- 0.001, respectively. The same comparison with pioglitazone and EGCG (and insulin) as comparered to pioglitazone (and insulin) demonstrated a 37% lowering. The effects of these compounds in adipocyte differentiation *in vitro*, were summarized as showing that "EGCG blocked [thiazolidinediones ("TZD")] TZD-induced adipocyte differentiation. Thus, the combination of EGCG and PPARγ ligand allows a pharmacological treatment that prevents progression of type 2 diabetes, while simultaneously minimizing side effects of PPARγ agonists." (Page 2, paragraph 21).

In Example 1C, the effects of EGCG and rosiglitazone were examined in a mouse model of type 2 diabetes *in vivo*. Applicants refer the Examiner to pages 3-4, paragraphs 25-35 including Tables 3-5. Although "[a]dministration of rosiglitazone significantly increased body weight and adipose tissue weight",.... "[c]ombined administration of EGCG and rosiglitazone totally abolished the increase in body weight and adipose tissue weight induced by rosiglitazone alone. Moreover, the combined administration resulted in a moderate reduction of body weight and adipose tissue weight compared to control mice. This effect was similar to the effect of the administration of EGCG alone." (Page 3, paragraph 29). Data is shown in Table 3 following paragraph 29. Favorable aspects of fasted state glucose testing and fed state plasma levels of glucose, triglycerides and free fatty acids testing is also set forth in paragraphs 30-34 including Tables 4 and 5. As summarized, "[t]he effects of rosiglitazone on plasma triglyceride and free fatty acid levels were maintained and glucose tolerance was further enhanced by co-administration of EGCG." (Page 4, paragraph 35, lines 8-11).

The results of this set of experiments showed that "EGCG as an adjuvant in the treatment of Type 2 diabetes and obesity with PPARγ ligands unexpectedly inhibits the adverse effects of treatment with the PPARγ ligands [sic] rosiglitazone while its beneficial effects were maintained or even enhanced." Thus, the specification discloses that the presently claimed composition provides unexpected and superior results, which would not have been obvious to the skilled artisan.

It is submitted that the findings for rosiglitazone further evidence the patentability of the claimed pharmaceutical composition. For this additional reason, the rejection should be withdrawn.

Regarding claim 17 and new claim 22, which recite dosage ranges of a pharmaceutical composition comprising (-) EGCG and comprising PPARγ ligand, respectively, Cui's health-benefiting beverage" fails to provide teaching, suggestion or motivation for the full range of dosages recited, about 10 mg to about 2000 mg (-) EGCG, and about 1 to about 1000 mg PPARγ ligand, respectively.

There are additional reasons supporting the patentability of new claim 23 wherein the pharmaceutical composition is a solid unit oral dosage form. Cui's "health-benefiting beverage" of herbs, botanicals or other natural ingredients provides no teaching, suggestion or motivation for formulating a pharmaceutical composition of the recited components, nonetheless in a solid unit oral dosage form.

In addition, the rejection is factually insufficient to support a rejection under § 103(a), as applied to the amended claims. In doing so we observe that obviousness cannot be based upon speculation, nor can obviousness be based upon possibilities or probabilities. Obviousness ***must*** be based upon facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When a conclusion of obviousness is not based upon facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993).

In making the rejection, the Examiner concluded, "It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a health-benefiting beverage comprising the instantly claimed components of

catechins found in green tea, such as epigallocatechin gallate, and ligustilide, found in Ligusticum wallichii based on the beneficial teachings of Cui." (Paper No. 20070713 at 8). As noted, claim 14 has been amended to recite that "the composition is a pharmaceutical composition." The claimed pharmaceutical composition is clearly not suggested by Cui's "health-benefiting beverage" of herbs and botanicals or other natural ingredients. Therefore, the Examiner's conclusion does not apply to the claims as amended. For this additional reason, the rejection should be withdrawn.

In view of the foregoing, it is respectfully submitted that the rejection has been rendered moot. Accordingly, withdrawal of the rejection is respectfully requested.

Therefore, for the reasons set forth above, entry of the amendments, withdrawal of the rejections, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, January 25, 2007.

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Respectfully submitted,

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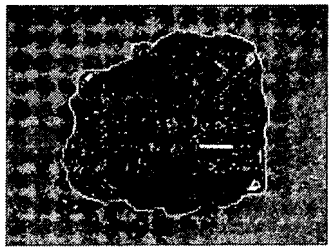
Glossy Ganoderma



Chinese Name	*Lingzhi*
Latin	*Ganoderma*
English Name	Glossy Ganoderma
Key Characteristics	Herb that tonifies *qi*
Source	Dried sporophore of *Ganodera licidum*(Leyss. Ex Fr.) Karast. or *Ganodera sinensis* Zhao, Xu et Zhang.
Property, Flavor and Meridians Entered	Sweet, neutral; Lung, Liver, Kidney
Action	To replenish *qi* and calm the mind, relieve cough and asthma

Indications	Dizziness, insomnia, palpitation, shortness of breath, asthenic cough and asthma in consumptive diseases, in addition, used for climacteric syndrome, impotence, coronary heart disease, chronic tracheitis, viral hepatitis and leucopenia
Chemical Composition	It contains polycose, sterol, triterpenes, amino acids, etc.

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